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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,155	SCEUSA, NICHOLAS A.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *4,5 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Office action is in reply to applicant's response of 8/22/2005.

Claims 1-13 are now pending in this application.

Newly submitted claim 13 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 13 recites a method for inhibiting the formation of histamine. Keeping in mind that the elected invention is directed to method for inhibiting the calcium ion excitation secretion cascade by administering at least one metal ion to an animal suffering from an autoimmune disease which causes secretions and eruptions via the calcium cascade, the newly added invention is distinct from the invention that has already been searched and examined and the additional search and examination burden represented by the additional distinct inventive concept would place an undue burden on the Examiner.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 13 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 4-5 stand withdrawn from further consideration as being directed to non-elected subject matter. Claims 1-3 and 6-12 will presently be examined *to the extent* that they read on the elected subject matter of record, i.e. Group I, wherein the animal to be treated suffers from an autoimmune disease which causes secretions and eruptions via the calcium cascade.

The Examiner again notes for the record that a method of inhibiting the calcium cascade comprising administering to an animal in need of treatment for the bullous form of impetigo an effective amount of mixture of zinc and copper metal ions (originally elected species) to block the calcium cascade is deemed to be allowable. The examination of the claims shall now continue with an expanded species scope, i.e. zinc or copper as the metal ion species.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for metal ions that have antimicrobial activity, which are administered to an animal that has a condition with an underlying or concomitant microbial etiology, such as for example the bullous form of impetigo, does not reasonably provide enablement for the full scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to a broadly defined mechanism (inhibit the calcium cascade) by which any animal suffering from an autoimmune disease which causes secretions and eruptions via the calcium cascade is effectively treated. It is not stated

in the claims whether the secretions and eruptions are internal or external. The claims are extremely broad as shown below.

Diseases encompassed	Active agents	Mode of administration
The elected invention is "autoimmune disease which causes secretions and eruptions via the calcium cascade." The specification only mentions the bullous form of impetigo. Other diseases could include lupus, scleroderma, inflammatory bowel diseases, psoriasis, autoimmune hepatitis, bullous pemphigoid, and many other diseases.	Claim 1: "at least one metal ion that blocks the calcium cascade" Claim 2: Zn, Cu, Mg, Mn, Fe, Al, mixtures thereof Note, the claims potentially read on almost 80% of the first 103 elements of the Periodic Table, since that many elements are metallic.	Claim 1: not specified Claim 6: nasal cavity Claim 7: through the mouth into the nasal cavity

The state of the art in treating various autoimmune diseases is that such diseases are some of the most difficult diseases to treat. There is no common treatment that is effective for the many different types of autoimmune diseases. Here, the diseases encompassed are divergent and are not known to be treated with one common type of medicine.

Even though the relative skill of those in the art is quite high given the medical degree necessary to practice medicine and treat patients with serious conditions as the above discussed autoimmune diseases, the unpredictability in the art is also quite high

due to the inability of science to find an effective treatment for the individual diseases, let alone a common treatment for all such diseases.

Unpredictability related to nasal or mouth-nasal cavity modes of administration is even higher. For example, impetigo is an infection of the skin. The claims read on nasally administering metal ions, or delivering metal ions across the mucous membranes of the mouth into the nasal cavity. In addition to the unpredictability involved for the reasons stated above, further unpredictability would result from such indirect administration of the metal ions.

In this context, the provided specification direction or guidance is quite sparse. Even though the same broad language as the claim language is used throughout the specification to describe the invention, no specific objective experimental result is provided to show that the metal ions of the invention, delivered via the nasal cavity or otherwise, would treat an animal "suffering from an autoimmune disease which causes secretions and eruptions via the Calcium cascade." Given the state of the art, the variety of divergent diseases encompassed by the claims, and the other factors discussed above, in the absence of any working examples one skilled in the art would be faced with undue experimentation in order to practice the invention to the full extent claimed.

Therefore, the claims are rejected as lacking in adequate enabling support.

Applicant's argument relative hereto, filed on 8/22/2005, reveals a lack of understanding of this ground of rejection. Applicant misses the main point of this ground of rejection in that the full claim scope (almost 80% of the first 103 elements, to treat lupus, scleroderma, inflammatory bowel diseases, psoriasis, autoimmune hepatitis, bullous pemphigoid, and many other diseases) is not enabled. Whether the metal ions are administered using the Teorell-Meyer gradient or via other means, the full scope of the claimed invention has not been enabled for the reasons stated above. If such difficult-to-treat diseases as divergent as lupus, scleroderma, inflammatory bowel diseases, psoriasis, autoimmune hepatitis, bullous pemphigoid are effectively treated by applicant's method (almost 80% of the first 103 elements via numerous administration means and routes), it is queried why applicant does not submit objective evidence to that effect to rebut this ground of rejection.

For the reasons of record and for the reasons stated herein, this ground of rejection must be maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New claim 12 recites "dosage form based upon Teorell-Meyer gradient of differing pH levels between the repository compartment and the recipient compartment." Applicant's incorporation by reference of U.S. Patent No. 6,414,033 is noted, but that does not solve the claim language problem here, which is the lack of clarity due to "based upon." How is it based, is it merely based on some small thread of common theory, is it strictly based on the claim language of U.S. Patent No. 6,414,033 (and if so, which claim(s)), etc. The nature of the "based" scope is unclear. Claim 12 is therefore unclear and indefinite.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kashirina in view of Mandell et al.

Kashirina explicitly discloses treating impetigo vulgaris and impetigo streptogenes with 10% syntomycin/zinc paste (translation page 2). 763 children were effectively treated clinically (translation page 3, lines 15-19).

Mandell et al. teach that the bullous form of impetigo comprises about 10% of all cases of impetigo (page 911, paragraph bridging left and right columns).

It is recognized that "inhibiting the calcium cascade" and "autoimmune disease which causes secretions and eruptions via the calcium cascade" features are not stated in verbatim language by Kashirina. However, applicant's specification is evidence that "blistering eruptions running sores such as the bullous form of impetigo" fall within such autoimmune disease, in the context of applicant's invention (see specification, page 6, paragraph 0019). Kashirina's patients had "oozing lesions," which were stopped by the zinc-containing paste (translation page 2, last two lines and the paragraph bridging translation pages 2 and 3). Hence, Kashirina's patients clearly had the type of bullous form of impetigo, which is readable on the instant claims. Further, because the same metal, zinc, was administered to the same patients for the same disease at dosage that cannot be distinguished, the same result of inhibiting calcium cascade must necessarily have been obtained.

For these reasons, one of ordinary skill in the art would have been motivated to treat the bullous form of impetigo with Kashirina's zinc-containing composition.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Applicant's arguments relative hereto have been given due consideration, but they were deemed unpersuasive. Applicant states that "It is unclear from Kashirina if the diphenhydramine was the effective agent, the zinc ions, or the synctomycin." Applicant further argues that "The zinc ion is merely one form of synctomycin, and may or may not have anything to do with successful treatment of impetigo." However, the prior art clearly used zinc paste-containing syntomycin to treat impetigo in 763 children. Applicant's claims requires no more than "at least one metal ion that blocks the calcium cascade," of which zinc is one such metal ion (see claims 1 and 2). In fact, the claims are in open claim language, "comprising," so applicant's claims are themselves open to administering other therapeutic agents. The Examiner's position is that the zinc ion containing composition used in the prior art would have been expected by the ordinary skilled artisan in this field to effectively treat impetigo in general and the bullous form of impetigo in particular. The claims are thereby fairly suggested.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN PAK
PRIMARY EXAMINER
GROUP 1600